

MAR 20 2014

stryker**510(k) Summary**

Date prepared: November 05, 2013

Submitter: Stryker Leibinger GmbH & Co. KG
Bötzingen Straße 41
79111 Freiburg
Germany

Contact: Jamshed Badarpura
Stryker Craniomaxillofacial
750 Trade Centre Way, Suite 200
Portage, MI 49002, USA
Phone: (269) 389-4260
Fax: (877) 648-7114
jamshed.badarpura@stryker.com

Proprietary Name: Stryker Pediatric Mandible Distractor

Common Name: Bone plate system

Proposed Regulatory Class: Class II

Product Codes: MQN – Bone Plate

Predicate Devices:

1. OsteoMed Pediatric Intraoral Mandibular Distraction System, Extended – K062851
2. KLS Micro Zurich Distractor (aka: Zurich Distraction System) – K010139
3. Leibinger Advance Internal Midface Distraction System – K092743

Intended Use:

The Stryker Pediatric Mandible Distractor is intended to be used for bone stabilization and lengthening of the mandibular body and ramus.

Indication for Use:

The Stryker Pediatric Mandible Distractor is intended to be used for bone stabilization and lengthening of the mandibular body and ramus. The Stryker Pediatric Mandible Distractor is indicated to correct congenital or post traumatic defects in the body and ramus of the mandible of neonates and children up to 4 years old.

Device Description:

The Pediatric Mandible Distractor (PMD) System is a distraction system consisting of the following major components: distractor with integrated footplates, a removable activation rod and an activation key. The distractor initially stabilizes and then gradually distracts the bone segments separated by osteotomy. The removable activation rod is connected to the distractor and provides the point of attachment for the external activation key used to initiate the distraction of the bone segments.

The Pediatric Mandible Distractor (Subject Device) includes the distractor body, integrated footplates, a sliding footplate, and the activation joint (to attach the activation rod). It is available in eight variants with two different distraction lengths (20 and 30 mm), right or left footplate configuration with footplate sizes having either a 2X2 or 3X3 hole pattern.

Technological and Operational Characteristics:

The Stryker Pediatric Mandible Distractor is similar to its predicate devices having the following technological and operational characteristics:

- **Material:** Both the subject device and the predicate devices are made of biocompatible titanium:
 - The subject device is made of commercially pure titanium (CP Ti) and stainless steel.
 - The Predicate Device N° 1 is made of titanium and nickel titanium.
 - The Predicate Device N° 2 is made of titanium alloy.
 - The Predicate Device N° 3 is made of titanium, titanium alloy, and stainless steel.
- **Design:** The design of the subject device is similar to the predicate devices. They all have the same components: body, footplates, activation joint (for activation rod connection). In addition, the subject device uses the same components and interfaces (e.g. activation rod) for distraction activation as the predicate devices. The subject device and its predicate devices offer various options of

- **Principal of Operation:** distraction lengths and footplate sizes. The footplates of the subject device are fully integrated (i.e. non-welded) compared to the predicate device N°1 (assembled), N° 2 (welded footplates), and the predicate device N° 3 (screwed footplates). The basic operational principle of the subject device as well as the predicate devices is for bone stabilization and lengthening. The method of site preparation and fixation is the same for both subject and predicate devices. The subject device and predicate devices are temporary implants.
- **Packaging:** The subject device and all predicate devices are dispensed non-sterile.

Clinical Testing:

No clinical testing was performed to support this submission.

Non-Clinical Testing:

Verification and Validation (V&V) evaluation has been performed on the Subject Device in the following categories: biocompatibility, corrosion, cleaning validation, sterilization validation, simulated aging, residual moisture after sterilization, bench testing (static and dynamic four-point bending test, compression force, distraction force tests), and handling of system (end use test). The Subject Device fulfilled all set acceptance criteria for each category in accordance with either ISO or ASTM specifications, or internally predetermined acceptance criteria if no standards were applicable. All applied ISO standards are listed below:

Reference	Title
Biocompatibility	
DIN EN ISO 10993 ff as valid 2013	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management system
Bench Testing	
ASTM F 382	Standard Specification and Test Method for Metallic Bone Plates
ASTM STP 731	Tables for Estimating Median Fatigue Limits
Sterility/Reprocessing	
ISO 11138-1:2006	Sterilization of health care products - Biological indicators - Part 1: General requirements
DIN EN ISO 11737-1:2009	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
DIN EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
DIN EN ISO 14161:2011	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results
DIN EN ISO 14937:2009	Sterilization of health care products – general criteria for characterization of a sterilizing agent and development, validation and routine control of a sterilization process
EN ISO 15883-1:209	Washer-disinfectors: General requirements, terms and definitions and tests
DIN EN ISO 17664:2004	Sterilization of medical devices – Information to be

Reference	Title
	provided by the manufacturer for the processing of resterilizable medical devices
DIN EN ISO 17665-1:2006	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
DIN ISO/TS 17665-2:2009	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1

Substantial Equivalence Conclusion:

The Stryker Pediatric Mandible Distractor is substantially equivalent to its predicate devices with respect to its intended use, design, materials and operational principle. Further, the performance testing confirms that the Stryker Pediatric Mandible Distractor is safe and effective for its intended use, and performs as well as the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Stryker Leibinger GmbH & Co. KG
C/O Mr. Jamshed Badarpura
Senior Regulatory Compliance Analyst
Stryker Craniomaxillofacial
750 Trade Center Way, Suite 200
Portage, MI 49002

Re: K133398

Trade/Device Name: Stryker Pediatric Mandible Distractor
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate System
Regulatory Class: II
Product Code: MQN
Dated: February 10, 2014
Received: February 14, 2014

Dear Mr. Badarpura:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

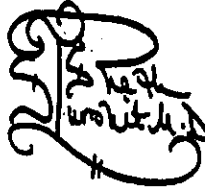
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGR1D

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133398

Device Name: Stryker Pediatric Mandible Distractor

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X

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K133398

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